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Reduced Levels of Fat in the Diet May Decrease the Risk of Breast Cancer Recurrence According to New Clinical Trial

Postmenopausal women who reduce their consumption of dietary fat and have been treated for early-stage breast cancer may reduce their chances for breast cancer recurrence or a second breast cancer, according to results from the Women's Intervention Nutrition Study (WINS). WINS was the first large-scale randomized trial to show that a change in diet can improve breast cancer outcomes in women who are receiving conventional treatment for early-stage breast cancer. Results of this study, which was sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health, appear in the December 20, 2006, issue of the *Journal of the National Cancer Institute** along with an editorial on the findings by NCI scientists**. This report is based on an interim analysis of the trial data.

The WINS study investigated a subset of women who have already been diagnosed with breast cancer and who were willing to enroll in a study to see if lowering fat in their diet would reduce the risk of their cancer recurring. Earlier in 2006, the Women's Health Initiative (WHI), which examined the effect of a low fat diet on breast cancer risk, showed a trend toward a modest benefit of a reduced-fat diet on the incidence of invasive breast cancer.

"The relationship between dietary fat and breast cancer has been unclear," said NCI Director John E. Niederhuber, M.D. "Certainly there is accumulating evidence that a healthy lifestyle — reduced fat consumption and exercise — is a worthy goal, to decrease risk and to optimize long-term therapy outcome."

WINS enrolled 2,437 women between 1994 and 2001 who had been treated for early-stage breast cancer. The women, ages 48 to 79, were randomly assigned to a lower-fat dietary intervention group or a control group who ate their regular diet.

At the start of the study, both groups consumed similar amounts of calories from fat; about 57 grams of fat per day or close to 30 percent of daily caloric intake. At the end of the first year of observation, the women in the dietary intervention group had reduced their fat intake by an average of 24 grams per day compared with only a 5

gram per day drop in the control group. The difference between the two groups was maintained throughout the trial. By the fifth year of the trial the women in the intervention group weighed an average of 6 pounds less than the women in the control group. Three more years of follow-up are currently being planned.

After a median of five years of follow-up, breast cancer recurrence or new breast cancers occurred in 9.8 percent of the women on the low-fat diet and in 12.4 percent of those on the standard diet. This amounted to a 24 percent reduction in the relative risk of recurrence for the women on the low-fat diet. The largest risk reduction — 42 percent — appeared to be among women on the low-fat diet whose tumors did not respond to the presence of the hormone estrogen. The risk reduction was 15 percent in women who did respond to estrogen. Breast cancer that doesn't respond to estrogen is called estrogen receptor negative (ER-negative) and usually has a poorer outcome than ER-positive disease. "Reductions were predicted in women with ER-positive disease because of the association between fat intake and estrogen levels but the effect on ER-negative disease is, if verified, a surprising and potentially important observation regarding breast cancer and signals a possible new avenue of research," said John Milner, Ph.D., Chief of the Nutritional Science Research Group at NCI.

"These results suggest that an intervention aimed at reducing dietary fat consumption can reduce the risk of breast cancer recurrence," said principal investigator Rowan T. Chlebowski, M.D., Ph.D., of the Los Angeles Biomedical Research Institute in California. "Although further confirmation is needed, a low-fat diet may offer other health benefits, such as modest weight loss."

"In both WHI and WINS studies, it took about four years to detect a reduction in risk so clearly these are not immediate effects," said Milner. "It is also clear that some women benefit a lot more than others from a reduction in dietary intake of fat, possibly because a person's genetics may well be setting the tone for the benefits of dietary intervention." He also emphasized that a reduction in fat is just one of many dietary modifications that may influence the development of cancer.

In the accompanying editorial, Anne C.M. Thiébaut, Ph.D., et al. at NCI, discuss various study limitations, including the use of self-report to track diet and possible imbalances in treatment between the two study groups. They also note the difficulty of conducting clinical trials where very dramatic lifestyle changes are involved, but conclude that WINS produced very important results for future consideration.

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For more information about cancer, please visit the NCI Web site at http://www.cancer.gov, or call NCI's Cancer Information Service at 1-800-4-

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*Chlebowski RT, Blackburn GL, Thomson CA, Nixon DW, Shapiro A, Hoy MK, et al. Dietary fat reduction and breast cancer outcome: interim efficacy results from the Women's Intervention Nutrition Study (WINS). *J Natl Cancer Inst* 2006; Vol. 98, No. 24, pp 1767-1776.

**Thiébaut ACM, Schatzkin A, Ballard-Barbash R, Kipnis V. Dietary Fat and Breast Cancer: Contributions from a Survival Trial. *J Natl Cancer Inst* 2006; Vol. 98, No. 24, pp 1753-1754.
